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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,045	01/11/2005	Daniel Rachlin	336-1102US	6611

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GREGORY SMITH & ASSOCIATES
3900 NEWPARK MALL ROAD, 3RD FLOOR
NEWARK, CA 94560

EXAMINER	
BOR, HELENE CATHERINE	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
05/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,045	RACHLIN ET AL.	
	Examiner	Art Unit	
	HELENE BOR	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *dictionary entry*.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. Claim 1, 3-7, 9, 11-13 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291), and further in view of Hayakawa et al. (US Patent No. 5,575, 291).

Claim 1, 3-7, 9, 11-13 & 19: Paton teaches an ultrasound imaging system (Figure 1, Element 1) having a scan head (Figure 1, Element 4) with at least one transducer (Figure 1, Element 6). Paton teaches the interface device being removable to the scan head (Col. 2, Line 40). Paton teaches a reservoir (Figure 1, Element F) with a proximal end and a distal end. Paton teaches where the reservoir is configured to maintain a fluid tight seal between the reservoir and the scan head [sealingly secured] (Col. 2, Line 46-47 & Figure 1, Element 7). Paton teaches a scan window (Figure 1, Element 16) located proximate the distal end of the reservoir through which ultrasound energy is transmitted and received (Col. 2, Line 43-44). Paton teaches a fluid tight seal (Figure 1, Element 7) between the scan window and the distal of the reservoir and a fluid acoustic coupling membrane located within the reservoir and filling a space between the transducer and the scan window (Figure 1, Element 7). Paton teaches wherein the transducer is allowed to transverse across an intended scan path with the reservoir (Col 3, Line 3-10). Paton fails to teach the scan window being made of solid, non-flowable hydrogel. However, Hayakawa teaches cross-linked [by freezing] hydrogel [hydrated] with greater than 50% water content (Col. 5, Line28-42) with less than 1dB/cm/MHz (Col. 1, Line 57-59) with a mesh support structure (Figure 3A, Element 60a), delivery of

fluid acustic coupling material to a distal surface of said scan window (Fig. 3G, Element 64) and polyethylene oxide (Col. 1, Line 43-44) because hydrogel material suffer less attenuation than non-hydrogel materials (Col. 1, Line 45-55). It would have been obvious to one of ordinary skill in the art to substitute the plastic membrane of Paton with the hydrogel material of Hayakawa in order to lessen attenuation (Col. 1, Line 45-55).

Claim 9: Paton teaches means for adjusting a distance between said scan window and the transducer to allow adjustment of a position of the scan window with respect to a focus of the transducer (Figure 1, Element 53 & 6 & Col. 1, Line 11-18).

Claim 11: Paton fails to teach a shaped scan window, however, Hayakawa teaches fitting the scan window to fit the profile of a body surface even with steep undulations (Col. 4, Line 1-4). Although Hayakawa does not specifically teach the scan window being contoured for the eye, the device is disclosed within Hayakawa as being capable of such a configuration for ensuring an accurate diagnosis (Col. 4, Line 3-4) and it would have been obvious to one of ordinary skill in the art to modify the system of Paton to include the body contouring of a desired part [an eye] as taught by Hayakawa for ensuring an accurate diagnosis (Col. 4, Line 3-4).

Claim 12: Paton teaches wherein the reservoir comprises a plurality of separate pieces between which the scan window is mechanically secured (Col. 3, Line 1-2).

2. Claim 2, 15 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291), and in view of Hayakawa et al. (US Patent No.

5,575, 291) as applied to Claim 1, 3-7, 9, 11-13 & 19 above, and further in view of Katsumata (US Patent No. 5,078,149).

Claim 2, 15 & 18: Paton and Hayakawa fail to teach sterilizing the interfacing device however, Katsumata teaches the interface device being sterile (Col. 5, Line 47-53) for use in surgical operations which require sterilization (Col. 5, Line 50-53). It would have been obvious to one of ordinary skill in the art to modify the system of Paton and Hayakawa to include the sterilization as taught by Katsumata for use in surgical operations which require sterilization (Col. 5, Line 50-53).

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291, and further in view of Hayakawa et al. (US Patent No. 5,575, 291) as applied to Claim 1, 3-7, 9, 11-13 & 19 above and further in view of Matthews (US Patent No. 3,939,123).

Claim 8: Paton fails to teach hydrogels and Hayakawa fails to teach the specific hydrogel composition. However Matthews teaches hydrogel formed from polyisocyanate terminated poly(alkrylene ether) polyols (Col. 2, Line 13-49). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Paton and Hayakawa to include the hydrogel composition as taught by Matthews in order to produce a hydrogel with high water absorbency (Col. 5, Line 1-6) because high water content reduces attenuation (Hayakawa; Col. 1, Line 57-59).

4. Claim 10 & 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291, and further in view of Hayakawa et al. (US

Patent No. 5,575, 291) as applied to Claim 1, 3-7, 9, 11-13 & 19 above and further in view of Puech (US Patent No. 6,837,855 B1).

Claim 10 & 14: Paton and Hayakawa fail to teach the focus range of the device or the range of 50 to 100 MHz. However, Puech teaches a device wherein the transducer focus is in the range of 2 to 6 mm past the distal the edge of the device [4mm] (Col. 2, Line 19-21) and the range of 50 to 100 MHz (Col. 2, Line 27-30) in order to verify the effectiveness of surgical act on the anterior segment of the eye (Col. 2, Line 50-55). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Paton and Hayakawa to include the transducer focus range as taught by Puech in order to verify the effectiveness of surgical act on the anterior segment of the eye (Col. 2, Line 50-55).

5. Claim 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paton et al. (US Patent No. 4,120,291, and further in view of Hayakawa et al. (US Patent No. 5,575, 291) as applied to Claim 1, 3-7, 9, 11-13 & 19 above and further in view of de Juan et al. (US Patent Application No. 2001/0029335 A1).

Claim 15-17: Paton and Hayakawa fails to teach the surgical instrument or access for the surgical instrument. However, de Juan'335 teaches the device incorporating a surgical instrument and an entry aperture (Figure 5A, Element 305a & 206, Figure 6A & 6B and Page 4, Paragraph 0042). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the system of Paton and Hayakawa to include the surgical instrument and entry aperture as taught by de Juan in

order for a surgeon to scan the retina during the procedure to evaluate the effectiveness of the action taken and for instrument introduced (Page 4, Paragraph 0042 & 0046).

Response to Arguments

6. Applicant's arguments filed 02/06/2009 have been fully considered but they are not persuasive. The previous Office Action mailed 08/06/2009 failed to explicitly rejected Claims 3, 5, 7 and 11 although it is noted the subject matter of the Claims was discussed within the written portion of the rejection itself. The Examiner regrets this error and the following Office Action has been corrected to clarify the rejection. Any remaining relevant arguments will be addressed below.

The Applicant submitted the argument that the gel material of Hayakawa is "barely solid" and "cannot support its own weight without water oozing out of the gel material" (Page 5 of Remarks filed 02/06/2009). However, the Examiner respectfully disagrees. Hayakawa teaches multiple embodiments of the hydrogel: a preferred embodiment with PVA having 99.0 mole % or over in the degree of saponification and an embodiment with PVA having less than 98.0 mole % in the degree of sapoification (Col. 4, Line 64-67). Hayakawa discloses, "When the PVA is less than 3 weight %, the gel material is poor in holding water and cannot be maintained in a specific shape" (Col. 5, Line 5-7). Hayakawa describes the preferred gel material as "hav[ing] a high tear strength" (Col. 8, Line 58-60), "not tacky" (Col. 7, Line 13), "will not remain on the body surface" (Col. 4, Line 56) and "the patient will not feel discomfort or need to remove remaining gel" (Col. 4, Line 59-60). The deficiencies identified by the Applicant are found in the alternative embodiment. The combination of the rejection is based on the

preferred embodiment of Hayakawa. Therefore, the alleged deficiencies are not present in the proposed combination. Hayakawa also discloses that it is desirable to substitute non-hydrogel material for hydrogel material (Col. 1, Line 45-55) to improve S/N ratios and have less attenuation (Col. 1, Line 45-44).

The Applicant submitted the argument that "In Hayakawa, the gel material itself is the coupling material, no coupling fluid is required, therefore there would be no motivation to modify the reference as suggested by the Examiner" (Page 6 of Remarks filed 02/06/2009). As the Examiner understands the argument being presented, the Examiner contends that the Hayakawa is not the base reference being modified. Rather the system of Paton et al. (US Patent No. 4,120,291) is being modified in light of Hayakawa (US Patent No. 5,575,291). The Examiner contends that modifying Paton in light of Hayakawa would not change the principle of operation of the modified system of Paton. The Examiner holds that the teachings of the references are thus sufficient to render the Claims *prima facie* obvious.

The Applicant submitted the argument that Paton does not disclose "means for adjusting a distance between said scan window and the transducer to allow adjustment of a position of said scan window with respect to a focus of the transducer". The Applicant contends that "the configuration of the oscillating mechanism ensures that the face 6 of the ultrasonic transducer probe 3 remains a constant distance from the membrane 16 at all times" (Page 7 of Remarks filed 02/06/2009). As is demonstrated below in the modified Fig. 6 of Paton [highlighted grey for emphasis], the centre point of the face 6 is substantially equidistant from the membrane; however not with regards to

the transducer as a whole. The Examiner contends that Hayakawa discloses means for adjusting a distance between said scan window and the transducer with respect to the transducer as a whole not just its centre point. Further this allows the adjustment of a position of said scan window with respect to a focus of the transducer as indicated by the sector scanning process also demonstrated in the modified Fig. 6.

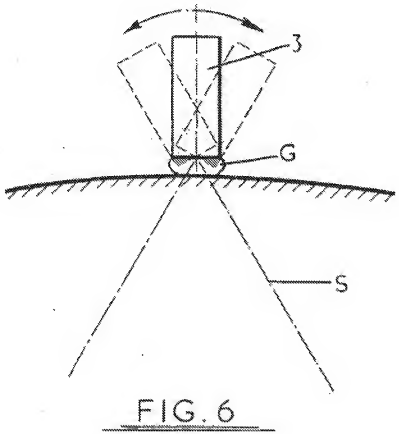

FIG. 6

The Applicant submitted arguments that that Hayakawa conforms to the body surface by deforming which is difference operating principle than having a preform concave curve that approximately matches the curvature of the patient's eye (Page 7 of Remarks filed 02/06/2009). The Examiner contends that the Claims make no distinction

between a preformed or deformed hydrogel and is broad enough to encompass either embodiments.

The Applicant submitted arguments that Paton does not teach "wherein the reservoir comprises a plurality of separate pieces between which the scan window is mechanically secured" (Page 8 of Remarks filed 02/06/2009). However, the Examiner contends that "[the] subassembly removable from the remainder of the housing along the line 101 by loosening the Allen screws 100 shown in Fig. 1" contained the separate pieces [Allen screws] that contains the reservoir [below 101] and mechanically secures. In Fig. 1 of Paton the scan window 16 is between the plurality of separate pieces [Allen screws 101] wherein in the scan window 16 is mechanically secured.

The Applicant submitted the arguments that the Examiner erroneously stated that Hayakawa discloses a cross-linked hydrogel with a mesh support structure (Page 8 of Remarks filed 02/06/2009). The Applicant argued that in searching through dictionaries, the Applicant was unable to find a definition that supported the Examiner's interpretation of "mesh". According the American Heritage Dictionary [copy of which enclosed herein], the Examiner notes the following accepted definitions:

a. Something that snares or entraps

b. The state of being so engaged

As Hayakawa discloses in Col. 8, Line 60-62, "Therefore, a strong coupling force is obtained by the integrated [engaged/snared/entrapped] formation, in which the gel material passed through holes 60a formed in the coupling member 60. The Examiner

contends that the structure disclosed by Hayakawa is structurally similar to that of the Applicants and functions in a similar manner to hold the hydrogel in place.

Applicant presented arguments with regard to Claim 15, which were addressed above in the revised rejection.

The Applicant presented the argument that one of ordinary skill in the art would not turn to look to Matthews for solution to problems encountered in ultrasonic imaging for eye surgery. The Applicant Claimed Matthews objective was to produce a fibrous absorbent material and this form of material is unsuitable for use as a scan window. The Examiner respectfully disagrees. Matthews disclosure in regards to the fibrous material is not in describing the invention of the disclosure but rather describing the prior art of irreversible absorbent materials. The fibrous materials that Matthews describes are in relation to diapers, bed pads and catamenials. Matthews then introduces hydrogel as a recent innovation in the art of materials with irreversible absorbents properties, but does not describe this invention as fibrous. Matthews objective is to disclose a hydrogel and its construction with desirable properties (such as high water absorbency and low water solubility (Col. 5, Line 26-28)], but does not describe the specific uses of the hydrogel. Since Paton and Hayakawa fail to teach all the specifics regarding cross-linked hydrogel composition, one of ordinary skill in the art would in fact turn to Matthews regarding hydrogels.

Regarding arguments with respect to Claim 10, the rejection above addresses these arguments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELENE BOR whose telephone number is (571)272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768